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m.m.
5/8/03

**TERMINAL DISCLAIMER TO OBVIATE DOUBLE PATENTING
REJECTION OVER A PRIOR PATENT**

In re Application of: Budny, John A. et al
Application No.: 09/875,997
Filed: June 06, 2001
For: "Compositions for Treating Cystic Fibrosis"
Docket Number: 1008-119.US

The owners*, John A. Budny and Matthew J. Budny, of the entire interest in the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application, which would extend beyond the expiration date of the full statutory term defined in 35 USC 154 to 156 and 173, as presently shortened by any terminal disclaimer, of prior Patent No. 5,871,714. The owners hereby agree that any patent so granted on the instant application shall be enforceable only for and during such period that it and the prior patent are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns.

In making the above disclaimer, the owners do not disclaim the terminal part of any patent granted on the instant application that would extend to the expiration date of the full statutory term as defined in 35 USC 154 to 156 and 173 of the prior patent, as presently shortened by any terminal disclaimer, in the event that it later: expires for failure to pay a maintenance fee, is held unenforceable, is found invalid by a court of competent jurisdiction, is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321, has all claims canceled by a reexamination certificate, is issued, or is in any manner terminated prior to the expiration of its full statutory term as presently shortened by any terminal disclaimer.

Check either box 1 or 2 below, if appropriate.

1. ☒ For submissions on behalf of an organization (e.g. corporation, partnership, university, government agency, etc.), the undersigned is empowered to act on behalf of the organization.

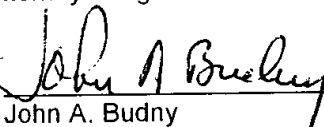
I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application of any patent issued thereon.

2. ☐ The undersigned is an attorney or agent of record.

Signature

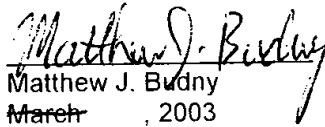
Name:

Date:


John A. Budny

~~March~~, 2003

April 4,


Matthew J. Budny

~~March~~, 2003

April 4,

☒ Terminal disclaimer fee under 37 CFR 1.20(d) included.

*Statement under 37 CFR 3.73(b) is required if terminal disclaimer is signed by assignee (owner).

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SUBJECT: DECISION ON TERMINAL DISCLAIMERS - FORMAL FORM

DATE: 5-9-03

APPL. S.N.: 091875, 997

TO EXAMINER: K. Wellington

ART UNIT: 1614

MOSE MONTGOMERY ROOM 11E18

MAILROOM DATE 5-5-03

AFTER FINAL YES ☐ NO ☒ NUMBER OF T.D(S). FILED 1

INSTRUCTIONS: I have reviewed the submitted T.D. with the results as set forth below. If you agree, please use the appropriate form paragraphs identified by this informal memo in your next office action to notify applicant about the T.D. If you disagree with my analysis or have questions at all about the acceptability of the T.D., please see me or our Special Program Examiner. THIS MEMO IS AN INFORMAL, INTERNAL MEMO ONLY. IT MUST NOT BE MAILED TO APPLICANT, NOR SHOULD A COPY BE LEFT IN FILE.

- ☐ The T.D. is PROPER and has been recorded. (See 14.23).
- ☐ The T.D. is NOT PROPER and has not been accepted for the reason(s) checked below. (See 14.24).
- ☐ The recording fee of \$ _____ has not been submitted nor is there any pre authorization in the application file to charge to a deposit account. (See 14.26.07)
- ☐ Application Examiner has not processed T.D. fee. (See fee authorization).
- ☐ The T.D. does not satisfy Rule 321(b)(3) in that the person who has signed the T.D. has not stated his/her interest (and/or the extent of the interest of the business entity represented by the signature) in the application/patent. (See 14.26 and 14.26.01).
- ☐ The T.D. lacks the enforceable only during the common ownership clause needed to overcome a double patenting rejection, Rule 321(c). (See 14.27, 14.27.01).
- ☐ It is directed to a particular claims(s), which is not acceptable since "the disclaimer must be of a terminal portion of the term of the entire patent to be granted". MPEP 1490. (See 14.26, 14.26.02).
- ☐ The person who signed the terminal disclaimer:
- ☐ has failed to state his/her capacity to sign for the business entity, (See 14.28).
 - ☐ is not recognized as an officer of the assignee, (See 14.29 and possibly 14.29.01).
- ☐ No documentary evidence of a chain of title from the original inventor(s) to assignee has been submitted, nor is the reel and frame specified as to where such evidence is recorded in the office. 37 CFR 3.73(b). (See 1140 O.G. 72). **NOTE:** This documentary evidence or the specifying of the reel and frame may be found in the T.D. or in a separate paper submitted by applicant. (See 14.30).
- ☐ No "statement" specifying that the evidentiary documents have been reviewed and that, to the best of the assignee's knowledge and belief the title is in the assignee seeking to take action. 37 CFR 3.73(b). (See 1140 O.G. 72) (See 14.31).
- ☐ The T.D. is not signed. (See 14.26, 14.26.3). or 14.26.03 if TD is not signed by all the owners.
- ☐ Attorney not of record in oath/decl. or a separate paper filed appointing a new or associate attorney. (See 14.29.01).
- ☐ The serial number of the application (or the number of the patent) which forms the basis for the double patenting is missing or incorrect. (See 14.32).
- ☐ The serial number of this application (or the number of the patent in reexam or reissue case(s) being disclaimed is missing or incorrect. (See 14.26, 14.26.04 or 14.26.05).
- ☐ The period disclaimed is incorrect or not specified. (See 14.27, 14.27.2 or 14.27.3)(For Samples 14.27.04 and 14.27.05)
- ☐ Other: _____
- _____
- ☐ Suggestion to request refund of \$ _____. (See 14.35, 14.36).

[] EXAMINER NOTE: IF APPLICATION IS IN CONDITION FOR ALLOWANCE ANY OF THE ABOVE INFORMALTIES MAY BE FAXED IN TO THE GROUP

FOR SAMPLE TERMINAL DISCLAIMERS AND CERTIFICATES:

- ☐ Sample of a TD over a pending application and assignee Certificate (See 14.37).
- ☐ Sample of a TD over a prior patent and assignee Certificate (See 14.38).
- ☐ Sample Assignee Certificate under 37 CFR 3.73 (b) (See 14.39)